

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application:
Inventor: Michael R. Hufford, et al.
Application No.: 09/825,533
Filed: April 2, 2001
Title: SYSTEM FOR CLINICAL TRIAL
SUBJECT COMPLIANCE

Confirmation No.: **9781**
Examiner: Martin A. Gottschalk
Group Art Unit: 3696
Customer No. **21971**

FILED ELECTRONICALLY ON: August 18, 2008

DECLARATION UNDER 37 CFR §1.131

M/S Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

We hereby declare that:

1. We are the inventors of the submitted subject matter as attached under the title of "Creation of training materials for a study configuration".
2. Prior to August, 2000, we had conceived and completed the invention as claimed in the U.S. patent application 09/825,533.
3. I further declare that all statements made herein of my knowledge are true and that all statements made on information and are believed to be true; and, further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under

Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Respectfully Yours,

Date: 18 Aug 2008

Michael R. Hufford

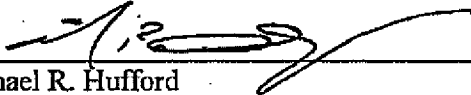
David Peterson

Jean A. Paty


Saul Shiffman

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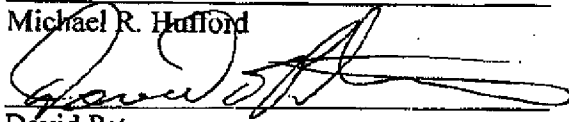
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Date: 18 Aug 2008

Michael R. Hufford

David Peterson

Jean A. Paty

Saul Shiffman

invivodata, inc.
Clinical Operations

STANDARD OPERATING PROCEDURE

Title: Creation of Training Materials for a Study Configuration	SOP Number: CO-3050	Page 1 of 3
	Last Revised: New SOP	Effective Date: [REDACTED]
Approved By/Date: [Signature] [REDACTED] Celeste A. Elash, Manager, Solutions Development [Signature] [REDACTED] Executive Vice President, Solutions Development		

1 Objective

To describe the SOP used to guide the configuration of site training materials for a particular study protocol.

2 Definitions

2.1 PED Patient Experience Diary

3 Procedure

3.1 *invivodata, inc.* uses a combination of visual presentations and training manuals to guide training of site personnel to conduct the following PED components of a clinical trial:

- 3.1.1 *invivosystem* PED operations
- 3.1.2 Subject training on PED use in the clinical trial
- 3.1.3 Patient Performance Evaluation

3.2 *invivodata, inc.* configures these training materials for each study to incorporate the components of that particular study protocol according to the sequence that follows:

3.2.1 Scientific Affairs delivers the signed study protocol to Clinical Operations as described in SOP SA-2010.

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Title: Creation of Training Materials for a study configuration	SOP Number: CO-3050	Page 2 of 3
	Last Revised: New SOP	Effective Date: [REDACTED]

3.2.2 Clinical Operations reviews the protocol to identify study-specific components, including, but not limited to:

- 3.2.2.1 Study design
- 3.2.2.2 Study treatment
- 3.2.2.3 Visit schedule
- 3.2.2.4 PED assessment content
- 3.2.2.5 PED assessment schedule
- 3.2.2.6 PED performance evaluation criteria

3.2.3 Clinical Operations delivers the outline of specifications for the above study-specific variables to Clinical Systems and Data Management for use in configuring their respective components of the training materials.

3.2.4 Clinical Operations incorporates the study-specific variables into the training materials for subject training on PED use in the clinical trial.

3.2.5 Clinical Systems revises the *invivosystem* PED operations training materials to incorporate the study-specific variables.

3.2.6 Data Management revises the Patient Performance Evaluation training materials to incorporate the study-specific variables.

3.3 The configured training materials are labeled with the study title and sponsor protocol number.

3.4 The configured training materials are labeled 'CONFIDENTIAL'.

3.5 Copies of the configured training materials are numbered.

3.6 These customized materials are used only for the purposes of training site personnel on PED-related procedures for a specific protocol.

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Title: Creation of Training Materials for a study configuration	SOP Number: CO-3050	Page 3 of 3
	Last Revised: New SOP	Effective Date: [REDACTED]

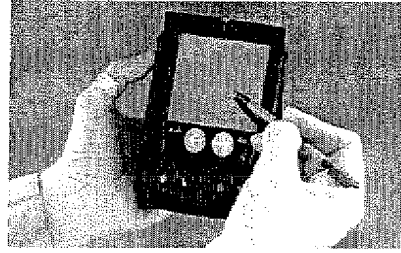
3.7 *invivodata, inc.* accounts for the return of all training materials from the site upon study closure.

4 Responsibilities

- 4.1 Scientific Affairs
- 4.2 Clinical Operations
- 4.3 Clinical Systems
- 4.4 Data Management

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invivosystem Training



Electronic Diary (ED) Training

Study Coordinator Manual

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A Multi-Center, Parallel, Randomized, Double-Masked,
Vehicle-Controlled, Dose-Ranging Study to Evaluate the

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[REDACTED]

[REDACTED]

[REDACTED]

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2100 Wharton St. • Suite 505

Pittsburgh, PA 15203

Phone (412) 390-3000 • Fax (412) 390-3020



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Study Clinic Visits

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Patient Management and Feedback

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 Sample Welcome Screen

 Sample Choose Activity/Study... Main

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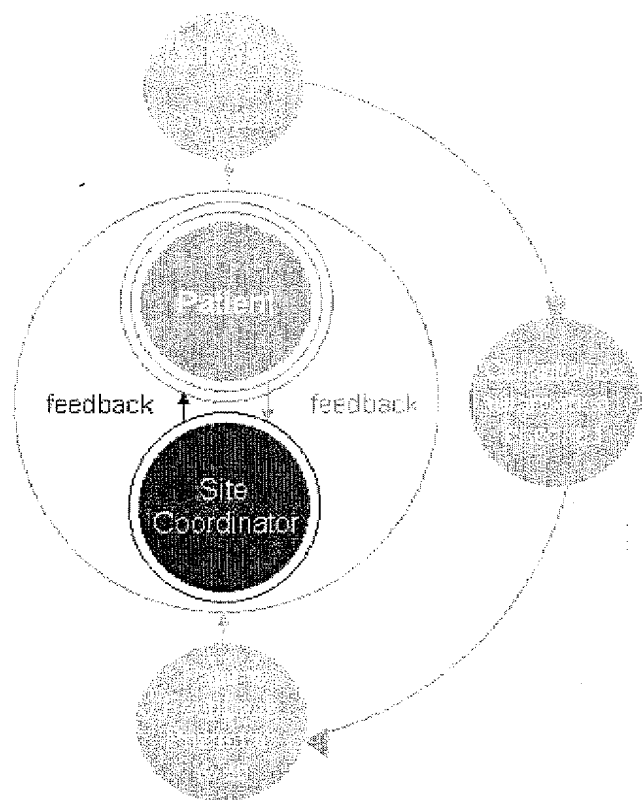
Using This Manual

Objective: To introduce you to Electronic Diary (called ED), a new way to collect patient self-data in the real world. To teach you how to use the invivosystem in this study.

We would like to introduce you to the *invivosystem* – a new way to collect patient self-report data in the real world. This goal of the system is to gather the most reliable and valid data from patients in real-time, as the patient goes about his or her daily routine.

Patients use an Electronic Diary (called ED) to record their experiences throughout the study. They send the data, using a data transfer kit, each night to a central location, where the data is automatically reviewed and summarized across a number of compliance-related variables. You – the study coordinator – can review these summaries and use them to track patients' progress in the study and ensure they comply with study procedures. The flow of the system is below

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The invivosystem is different than typical diaries. The ED is *very* easy to use, and it helps the patients comply with the protocol. The data cycle of patients collecting self-report data, and the study coordinator delivering regular feedback about the patient's compliance is key to the study success, thus, both the patient and study coordinator play critical roles. Put simply, the focus of this system is helping patients succeed in the clinical trial protocol. This manual explains the system, as well as the roles of the patients and study coordinators in collecting real-time, real-world patient self-report data.

Manual Overview

If you are using this manual on your own, we recommend that you work through it from beginning to end. Upon completing the homework (outlined in Chapter 5), you will be ready and qualified to use the invivosystem in this study.

The manual is divided into the following sections:

Chapter 2 explains the invivosystem® and all of the key components.

Chapter 3 describes how the invivosystem® fits into this trial's study flow.

Chapter 4 details the procedures for using the system to conduct this trial - from the time a patient enters the study until her termination or completion.

Chapter 5 describes the 'homework' that you must complete to become qualified to execute these procedures. You will not have access to the official study website until your homework is complete.

Chapter 6 outlines some frequently asked questions.

Getting Started

TIP

Use the left and right margins of this manual to take notes.

You will need to accomplish several things to ensure that invivosystem will function appropriately in your office.

This section describes the materials you'll need to get everything set up correctly, what to check for on your PC, and the setup tasks that invivosystem requires.

These steps summarize what you'll do next:

1. First, gather the materials you'll need:
 - a. This manual
 - b. Patient ED Training Flipbook
 - c. ED
 - d. Data Transfer Kit
 - e. A Windows-based PC
2. Check to see if your PC has Internet Explorer (IE) 5.5 installed. If you don't have IE 5.5 installed, you'll need to install it on your PC.
3. Identify a location with a phone jack and outlet plug.
4. Set up the Data Transfer Kit.
5. Visit the invivosystem.com Website.

Installing Internet Explorer

The invivosystem® uses Internet Explorer (IE), version 5.5 as one of its components. If you have IE on your PC, you should still check to see that it is version 5.5 (or higher). If you have IE 5.5 on your PC, you can go directly to the Setting Up the Data Transfer Kit section. Otherwise, you should follow the instructions in the Checking your PC for IE 5.5 to check for the right version of IE.

If you need to install IE 5.5 on your PC, then go directly to the Installing IE 5.5 from a CD-ROM or Downloading IE 5.5 from the Internet sections.

Checking your PC for IE 5.5

1. Open your current version of IE.
2. At the top of the screen, click Help.
3. From the Help menu, select About Internet Explorer.
4. Your version number is displayed immediately after Version: as an 11-digit number (for example x.xx.xxxx.xxxx).
 - a. If the first three numbers are smaller than 5.50, then you do not have IE 5.5 and should in the remaining steps in this section to install IE 5.5.
 - b. If the first three numbers are 5.50 or greater, then you are fine and can continue directly to the Setting Up the Data Transfer Kit section.

Installing IE 5.5 from a CD-ROM

1. Insert the IE 5.5 CD-ROM into your PC's CD-ROM drive.
 - a. The CD-ROM starts automatically.
2. If the CD-ROM does not start automatically, then
 - a. Click the Start button on the Task bar and select Run.
 - b. At the prompt, type: d:\cdsetup.exe (d is the CD-ROM drive indicator)
 - c. Click OK and follow the on-screen instructions.

Downloading IE 5.5 from the Internet

1. Go to
www.microsoft.com/windows/ie/download/ie501sp1.htm
2. Read the How to Download and Install instructions.
3. Click the Download Now button.
4. After the IE 5.5 software is installed, you must restart your PC.

Setting Up the Data Transfer Kit

Ensure that you perform the following setup steps before continuing to the next chapter.

1. Identify a location next to an analog phone jack and power outlet. (Fax lines will work.)

2. From the Data Transfer Kit, take out the phone splitter. (See the associated figure.)
3. If a phone is plugged into the phone jack:
 - a. Unattach the phone cord from the phone jack.
 - b. Plug the phone splitter into the phone jack.
 - c. Plug the phone cord into the empty slot on the splitter.
 - d. Go to Step 5.
4. If the phone jack is empty:
 - a. Plug the phone splitter into the phone jack.
 - b. Go to Step 5.
5. Plug the Data Transfer Kit power cord into the power outlet.
6. Look in the black bag, you should see small lights come on. (If lights are not on, reach into the bag and flip up the small, metal switch on the back of the modem.)
7. Place ED on the cradle. (The green light on the cradle should come on.)

Visiting the [invivosystem.com](http://www.invivosystem.com) Website

During this study, you will visit the [invivosystem.com](http://www.invivosystem.com) Website to track patients, review protocol compliance and data-related issues for your patient.

To visit the [invivosystem.com](http://www.invivosystem.com) Website:

1. Open IE 5.5.
2. In the URL Address area, type: <http://www.invivosystem.com>
3. Press the Enter key on your keyboard.

If you need assistance call your CRA or the invivodata Homework Help Desk at (412) 697-0161.

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CHAPTER 1: USING THIS MANUAL

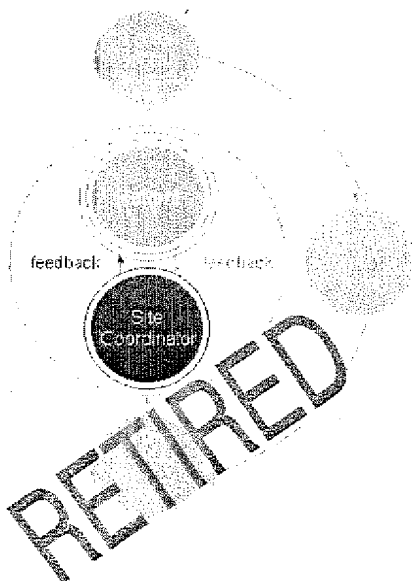
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Teaching and Managing Patients

Objective: To help you understand how to teach patients to use ED and how you will manage their feedback.

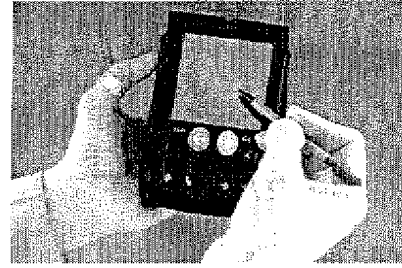
The invivosystem is based upon a Data Cycle with two key components:

- **Patient Self-report:** Patients are taught to use ED to self-report their real-time experience.
- **Patient Management and Feedback:** Using ED and the website, study coordinators are able to track patients and review their protocol compliance. The coordinators may also use data regarding patient management to make protocol decisions, depending on the specifics of a particular study. Study coordinators then give patients feedback on their compliance with the protocol on a regular basis.



Patient Self-Report

The data collection begins when patients are trained by site staff to use ED. Patients then use the ED as directed during their normal daily routine. At the end of each day, the patient puts ED in its 'cradle,' during which time the batteries recharge and ED automatically sends the day's data to a central location at invivodata. The next day, the patient wakes up and also then 'wakes up' ED for the day



Patient Management and Feedback

The invivosystem uses patient data entered into ED to create web-based profiles of each patient's performance. You can access this information on the invivosystem website (www.invivosystem.com) to track patient performance and help you manage the patients throughout the trial. The information is presented as reports that can be used to assess and encourage compliance. Other reports are designed to highlight questions about the data that need to be clarified.

Patient Management is broken into four parts:

1. Patient Tracking
2. Protocol Compliance
3. Problem/Issue Identification
4. Feedback

Patient Tracking

The invivosystem allows site coordinators and monitors to see how patients are complying with using ED in their day-to-day lives. Patient tracking is done by accessing ready-made data transfer reports on the invivosystem website.

Protocol Compliance

A very important component of managing patients is reviewing their compliance with the protocol. Summary compliance reports are available on the website that allow study coordinators to know how patients are doing. These reports guide

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the feedback that coordinators give patients about their compliance with ED's protocol

Issue Identification

If any problems or issues arise during data collection with ED that might require comments or changes to the database, the invivosystem® website allows site staff, CRAs, or invivodata staff to raise issues using the *comment* feature on the website

Feedback

Successful patient feedback involves two steps

1. Study coordinators review the summaries and reports on the website to track patients' progress and evaluate the patients' compliance.
2. The study coordinators draw on the good relationship they have with the patient to give feedback about compliance with ED's protocol.

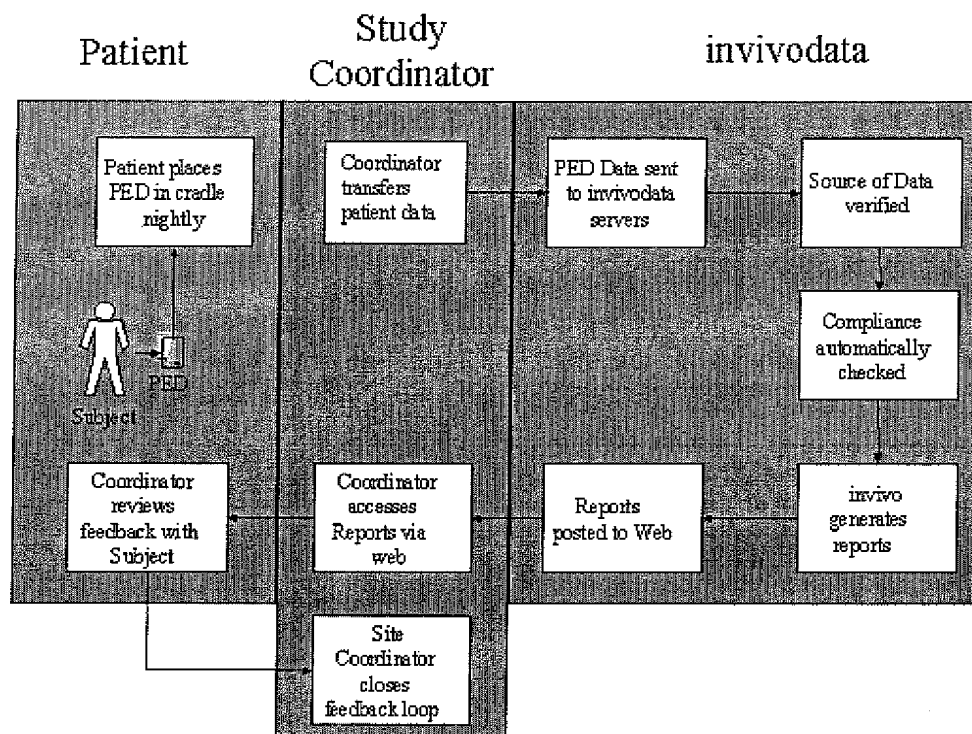
The invivosystem® in Action

The figure below shows in greater detail the flow of information throughout the system.

The process by which patients are tracked and receive feedback about their behavior includes the following steps

1. The patient uses ED to record their ~~ED~~ symptoms
2. The patient places ED in the cradle and ED transfers data during sleep
3. Data is automatically checked for compliance
4. Results are posted as reports on the web site
5. The Study Coordinator reviews the reports
6. The Study Coordinator uses the reports to give patients feedback
7. The Study Coordinator closes the feedback form on the web site

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PATIENT TRACKING PROCESS AND FEEDBACK... the process by which patients are tracked and receive feedback.

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The invivosystem and Study Flow

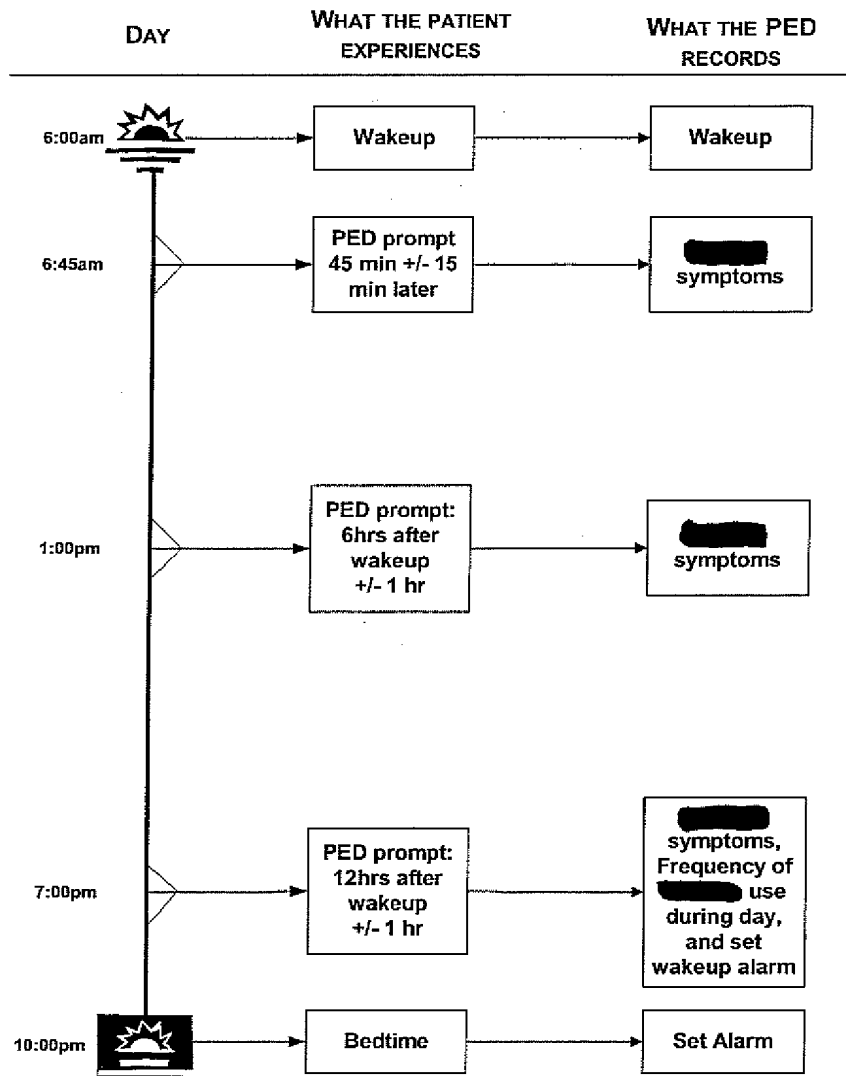
Objective: To understand how the invivosystem Data Cycle relates to the patients' daily interactions with ED and the study flow.

In this study, patients will use ED to record their symptoms and Refresh use on some weeks (**On monitoring periods**) and on other weeks they will not use the ED (**Off monitoring periods**). The ED, itself, will let the patients know when it is time to begin and end the monitoring periods throughout the trial.

Patient Daily Activities

The following figure illustrates a sample day in the life of a patient during the **On monitoring period** of the protocol. The assessment times listed are for illustration purposes only – the actual times of day the ED prompts each patient to complete the study assessments are based on the individual patient's wakeup time each morning.

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SAMPLE DAY IN THE LIFE OF A PATIENT... Shows interview completion during an ON MONITORING period.

Patient Study Flow

During this protocol, patients will spend some days on monitoring (using ED each day) and some days off monitoring (leaving ED in the cradle). ED will prompt patients when to start and stop monitoring. The study flow for patients is described below

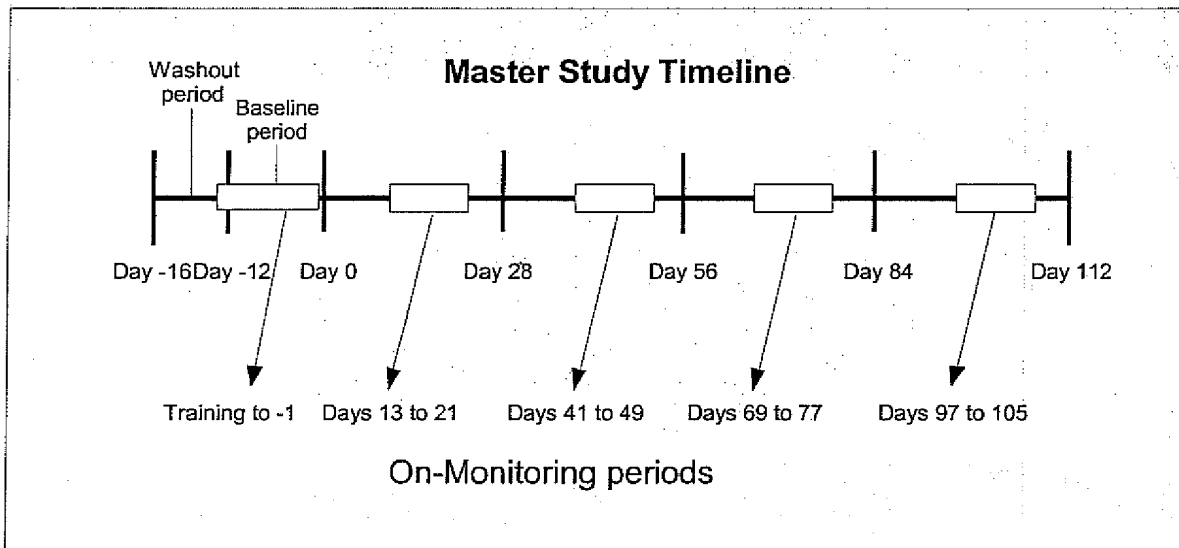
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On monitoring: ,

Patients: During On monitoring periods, ED will prompt the patient to complete the Morning, Afternoon, and Evening Reports.

Study coordinators: The study coordinator will review the website one day into the On monitoring period to confirm the patient started On monitoring as directed. The coordinator will also check the website three days into every On Monitoring period for feedback on the patient's compliance with the ED protocol (Patient Management). The coordinator uses the website information to call the patient if she didn't start On monitoring as directed, and to give the patient feedback about ED compliance (Patient Feedback).

The timeline for the on/off monitoring periods is shown below.



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Training Visit Day -16 to Day-12

1. At this visit the patient will be trained to use ED and follow study procedures.
2. At the end of the training visit, you will enter Coordinator Administration, select the Post Training Button and follow ED's instructions.

First On Monitoring Period: Training to Day -1

1. This on-monitoring period will begin immediately after the patient completes the ED training. The patient will complete the Morning, Afternoon, and Evening Reports daily, and the ED will automatically transfer data nightly.
2. Three days into this monitoring period, you will review the website to review the compliance reports and the Patient Performance Feedback Form (PPF).
3. You will call the patient to deliver the feedback on the PPF
4. Once you have delivered the feedback to the patient, you will close out the PPF on the invivosystem® website

Baseline Visit: Day 0

1. Prior to the patient's visit, you will access the invivosystem website and view the patient's reports and any open PPFs.
2. The patient will return to the clinic for a visit.
3. You will enter Coordinator Administration on ED, select the Day 0 Visit button, and follow ED's instructions. *Choosing the Day 0 Visit button will set the patient's monitoring schedule for the training period, so be certain you only select this button on the patient's Day 0 visit.*
4. If the patient qualifies to continue, ED will instruct you to enter the patient's randomization ID into the ED.
5. If the patient does not qualify to continue, ask the patient to return ED and the Data Transfer Kit.

Second On-Monitoring Period: Day 13 to Day 21

1. The patient will complete the Morning, Afternoon, and Evening Reports daily, and will transfer data nightly.

2. One day into the monitoring period, you will review the website to ensure the patient has started On-monitoring. If the patient did not respond to the On-Monitoring prompt and did not set the wakeup alarm, invivodata will post a PPF on the website to let you know.
3. If you find this PPF on the website, you will make a phone call to confirm the patient has started to use ED
4. Three days into this monitoring period, you will check the website to review the compliance reports and the PPF
5. You will call the patient to deliver the feedback on the PPF.

Third On-Monitoring Period: Day 41 to 49

6. The patient will complete the Morning, Afternoon, and Evening Reports daily, and will transfer data nightly.
7. One day into the monitoring period, you will review the website to ensure the patient has started On-monitoring. If the patient did not respond to the On-Monitoring prompt and did not set the wakeup alarm, invivodata will post a PPF on the website to let you know.
8. If you find this PPF on the website, you will make a phone call to confirm the patient has started to use ED
9. Three days into this monitoring period, you will check the website to review the compliance reports and the PPF
10. You will call the patient to deliver the feedback on the PPF.

Fourth On-Monitoring Period: Day 69 to Day 77

11. The patient will complete the Morning, Afternoon, and Evening Reports daily, and will transfer data nightly.
12. One day into the monitoring period, you will review the website to ensure the patient has started On-monitoring. If the patient did not respond to the On-Monitoring prompt and did not set the wakeup alarm, invivodata will post a PPF on the website to let you know.
13. If you find this PPF on the website, you will make a phone call to confirm the patient has started to use ED
14. Three days into this monitoring period, you will check the website to review the compliance reports and the PPF
15. You will call the patient to deliver the feedback on the PPF.

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Final On-Monitoring Period: Day 97 to Day 105

1. The patient will complete the Morning, Afternoon, and Evening Reports daily, and will transfer data nightly.
2. One day into the monitoring period, you will review the website to ensure the patient has started On-monitoring. If the patient did not respond to the On-Monitoring prompt and did not set the wakeup alarm, invivodata will post a PPF on the website to let you know.
3. If you find this PPF on the website, you will make a phone call to confirm the patient has started to use ED
4. Three days into this monitoring period, you will check the website to review the compliance reports and the PPF
5. You will call the patient to deliver the feedback on the PPF.

Weeks One, Four, Eight and Twelve Visits (occur between On monitoring periods)

1. At each of these visits, the patient must bring ED to the clinic.
2. Before the visit, you will check the website to review the compliance reports and a PPF that will be posted at the end of the most recent monitoring visit.
3. You will turn on ED and confirm that you want to complete a study visit now.
4. Enter Coordinator Administration, select the Other Visits button, and follow ED's instructions to transfer the patient's data during the clinic visit.
5. You will deliver the feedback listed on the PPF.

Final Study Visit: Day 112 (or Early Discontinuation)

1. At this visit you will take ED from the patient, enter Coordinator Administration, select the Final Visit button and follow ED's instructions.
2. You will keep ED and the Data Transfer Kit.
3. Place ED in the original Palm box with the cradle.
4. Use the retained packing material to pack the palm box.
5. Use the provided airbill to return the ED [REDACTED]

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CHAPTER 3: THE INVIVOSYSTEM AND STUDY FLOW

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Using the invivosystem

Objective: To learn the steps necessary to carry out the study procedures described in the previous chapter.

This section is organized by ED related patient and study coordinator activities from the time a patient enters the study until completion (or termination).

The materials you...

1. This manual
2. An ED ...
3. A Data Transfer Kit
4. The Patient Training Flipbook
5. The User's Guide

Setting Up Before the Training Visit

In this section, you will learn how to prepare an ED for a patient, how to interact with ED as the study coordinator, and how to use ED during study visits.

The steps for the training visit are as follows:

1. Setup a data transfer kit for the patient
2. Prepare an ED for the patient
3. Train the patient
4. Send the patient home with ED and the Data Transfer Kit

Ensure that you have accomplished all the tasks in Chapter 1's Getting Started section before you begin setting up before the first training visit.

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CHAPTER 4: USING THE INVIVOSYSTEM

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Preparing an ED for the Patient

The steps and figures below show you how to prepare an ED for a patient.

Note

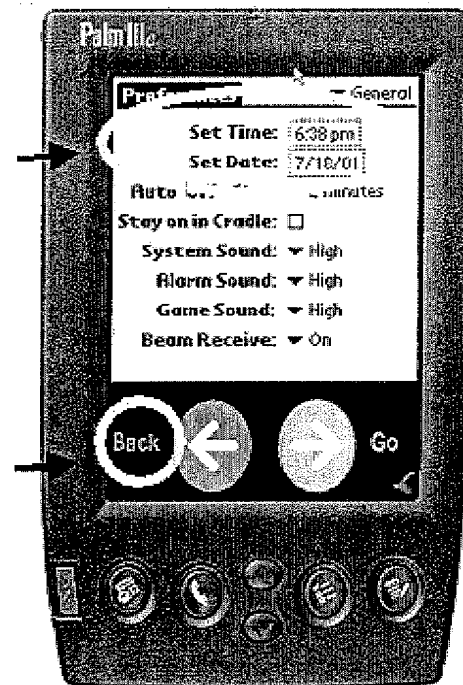
You should set up ED early on the day you train the patient.

1. Turn on ED by pushing the button indicated in the figure.



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2. Confirm date and time, tap 'B' in the word back.

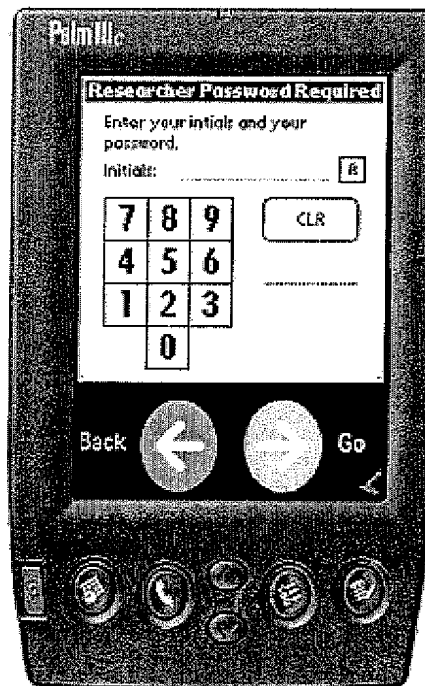


2. Select the IVD icon.

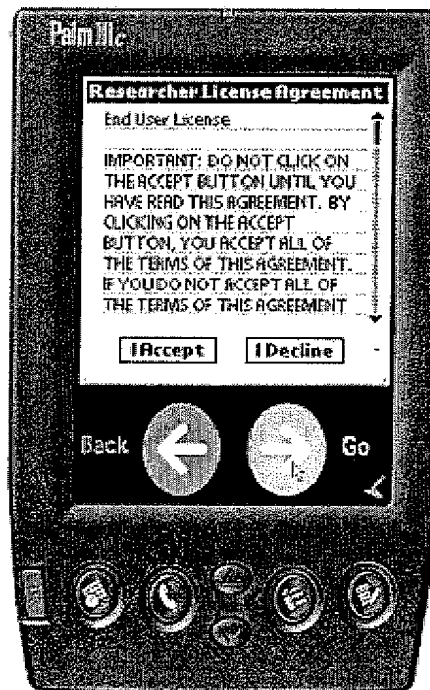


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3. Enter your initials and password as it appears on your electronic signature certificate.

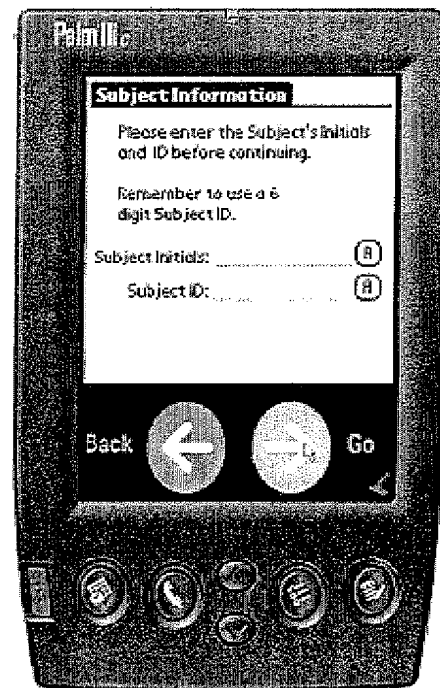


4. Accept the Coordinator License Agreement

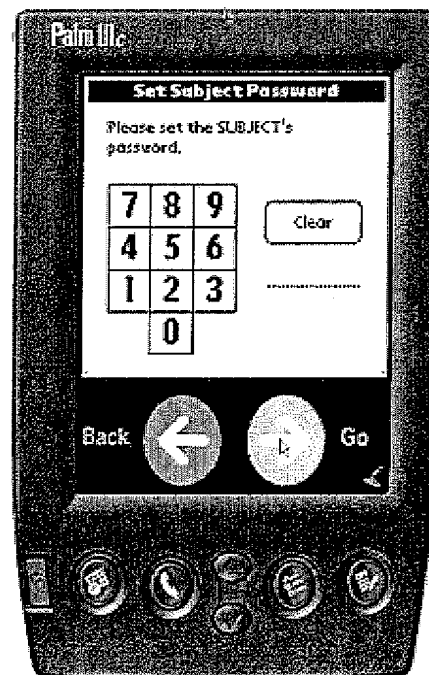


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5. Enter the patient's initials and password

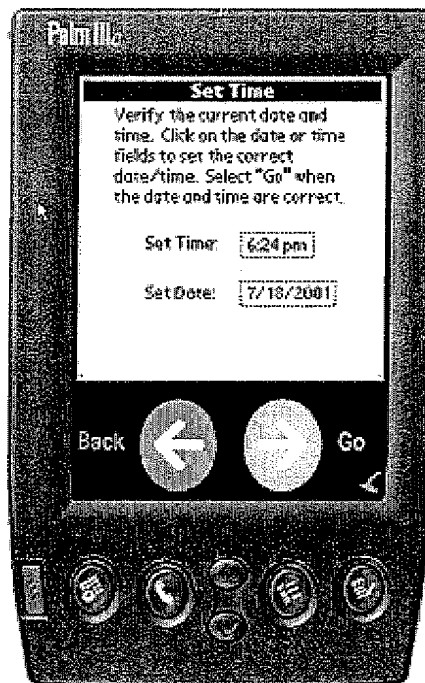


6. Set patient password. (use the password the Patient chose when he/she signed the Electronic Signature Certificate during Visit 1).

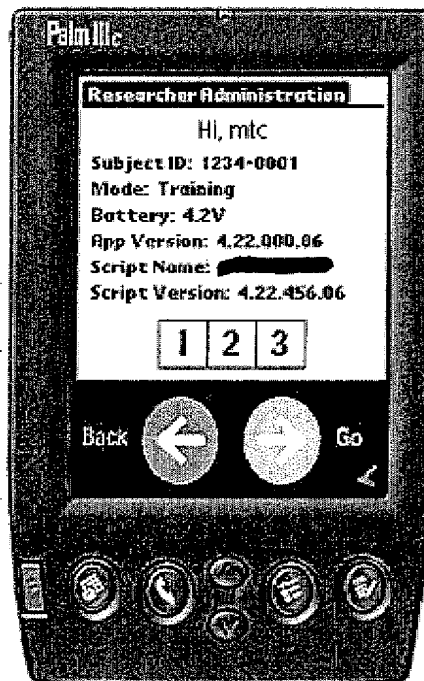


RETIRED

7. Verify the date and time and tap GO button.



8. Leave at 1-2-3 screen until ready to train the patient.



RETIRED

Training the Patient to use ED

Now that you've set up an ED for a patient, you'll learn how to train the patient and send him home with ED and the charging cradle.

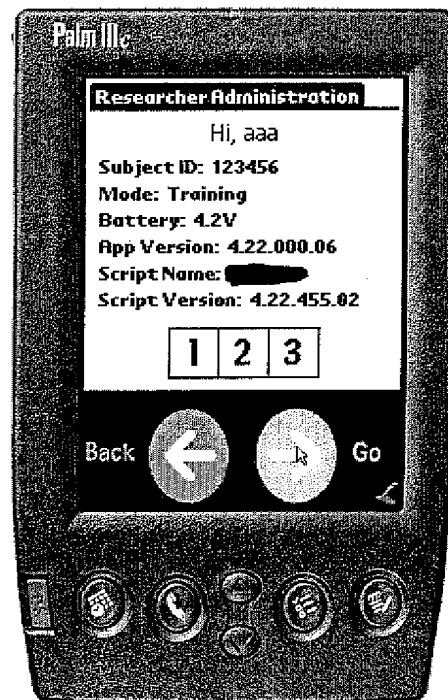
Following informed consent, and before you begin to train the patient, please have the patient complete an Electronic Signature Certificate (you will use this information during ED set up).

- To train patients to use ED, you will use a scripted flipbook presentation (in the ED Patient Training Flipbook) that guides you and the patient through a step-by-step training routine. At key points in the flipbook presentation, the patient will get hands-on practice completing the interviews on ED.

Starting the ED for training

The steps and figures below show you how to move the ED beyond the 1-2-3 screen.

1. Tap 1-2-1-2-3 in the 1-2-3 boxes.

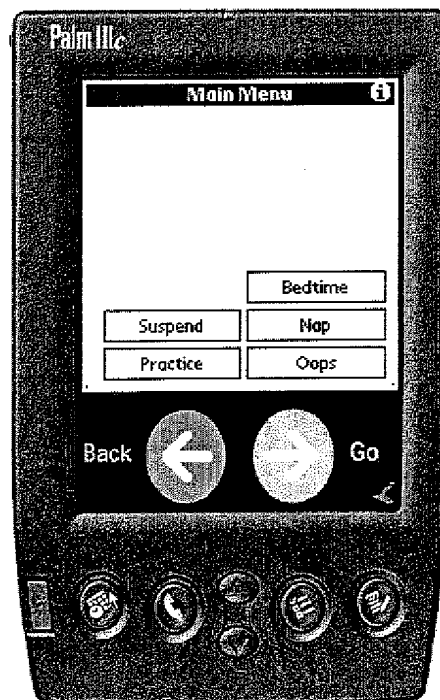


RETIRED

2. The patient reads and accepts the license agreement.



3. The Main Menu appears



RETIRED

Training Patients with the Flipbook

The ED Patient Training Flipbook is a scripted presentation that will guide your training presentation with the patient. You set the binder up as if it were an easel. The pictures face the patient and the text faces you. Follow the script to ensure a standardized presentation across all patients

Training Overview

The ED Patient Training Flipbook is a quick, concise reference that covers training in six easy steps.

1. Introduce ED
2. Introduce Interviews
 - a. Morning Report
 - b. Afternoon Report
 - c. Evening Report
 - d. On-Monitoring reminder prompt
3. Putting ED to Bed
 - a. Set ED's wake up alarm
 - b. Place ED in the cradle overnight
4. Review Other Options
 - a. Oops
 - b. Nap
 - c. Practice
 - d. Suspend
5. Practicing the Interviews
6. Test Transfer
 - a. To be completed by the patient upon returning home immediately after Training Visit.
7. Summary

RETIRED

Setting ED to Run-in Mode

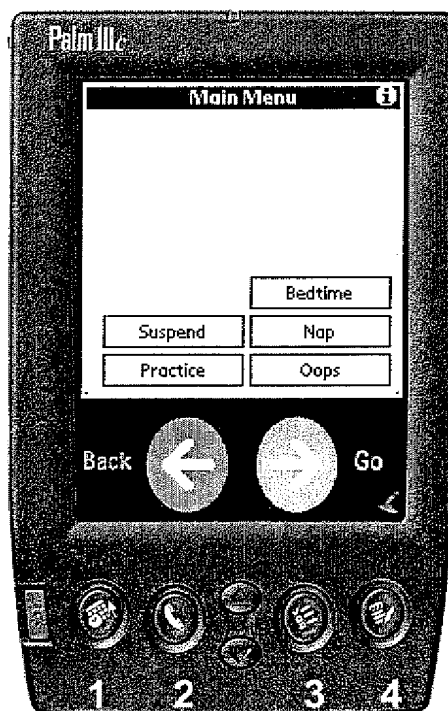
After the patient has been trained, there are a few more critical steps to complete before the patient can use ED in the study. You will be asked a series of questions and you will then perform a data transfer.

IMPORTANT!

When you train a patient on ED, ED will be in Training mode. By completing the Post Training button routine, and then selecting the Return to Patient button, you will change the software into "Run-in" mode, which is where ED will stay until the Day 0 Visit. ***This is a critical step, so please be sure to remember to select the V1 Post Training button, then the Return to Patient button BEFORE giving the ED to the patient to take home.***

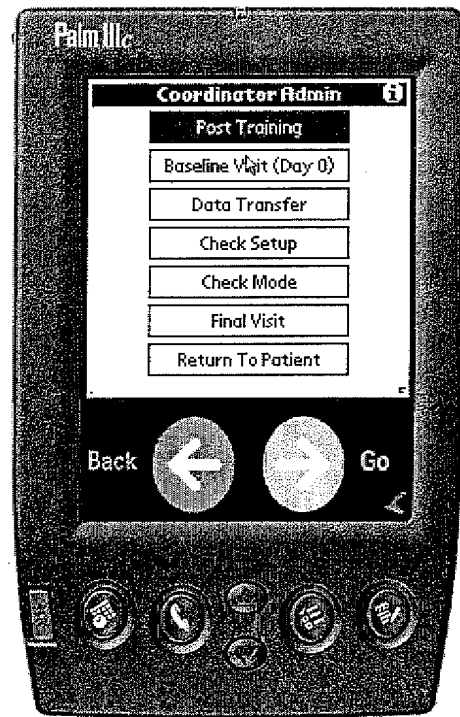
The steps and figures below show you how to complete these critical steps.

1. At the Training Main menu, use ED's lower buttons as numbers (ED's lower buttons also function as numbers, as indicated in the figure) to enter the 2-3-3-4-2 access code. These numbers allow you to enter Coordinator Administration.

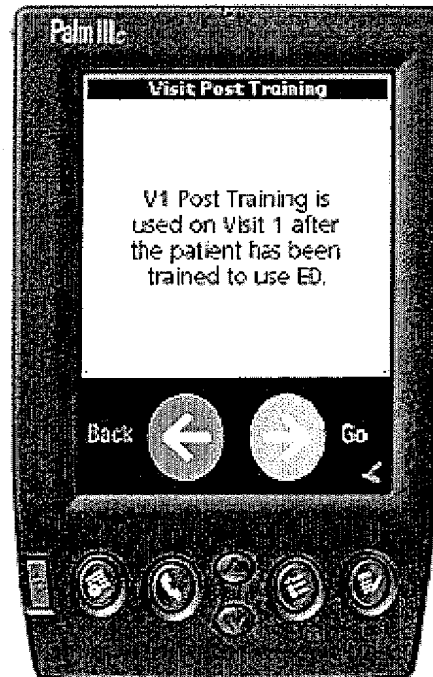


RETIRED

2. Choose the V1 Post Training Button and tap Go. (The V1 Post Training Visit Button is used at the end of the clinic visit after the patient has been trained in the protocol and using ED.)



3. Answer questions and follow ED's instructions on the next few screens (including a data transfer).

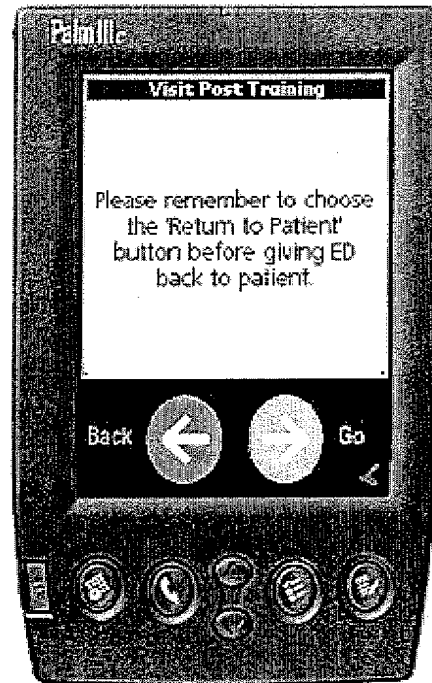


RETIRED

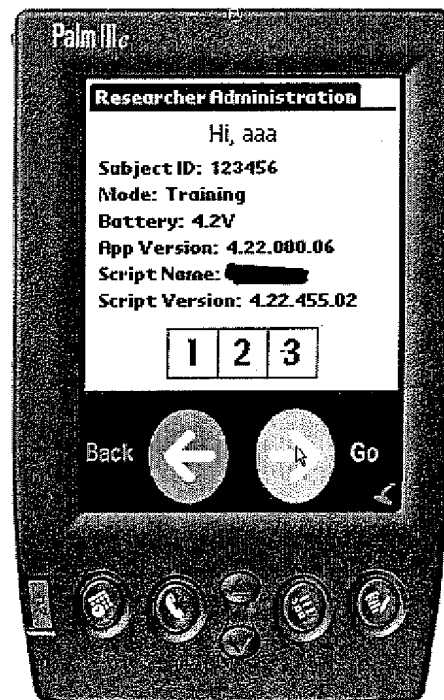


RETIRED

4. Select the Return to Patient Button.



5. Enter the 1-2-1-2-3 access code to start the patient software (confirm the software is starting in Run Mode).



RETIRED

Study Clinic Visits

The following sections describe how you'll use ED during clinic visits.

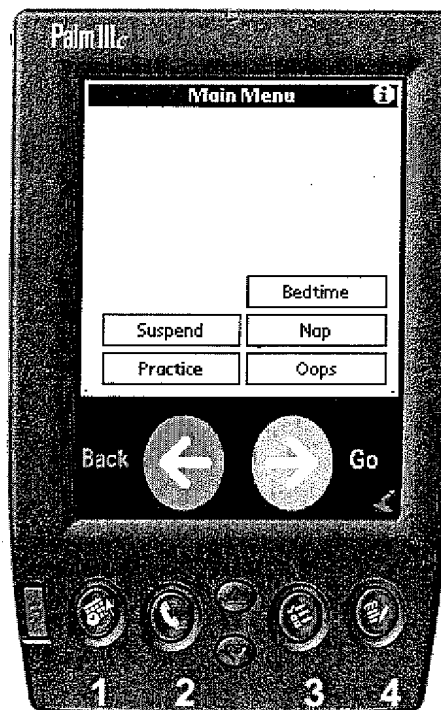
Training Visit: Day -16 to Day - 12

Remember, at this visit the patient will be trained to use ED and follow study procedures. At the end of the training visit, you will enter Coordinator Administration, select the Post Training Button and follow ED's instructions. Follow the instructions beginning on page 32.

Day 0 Visit:

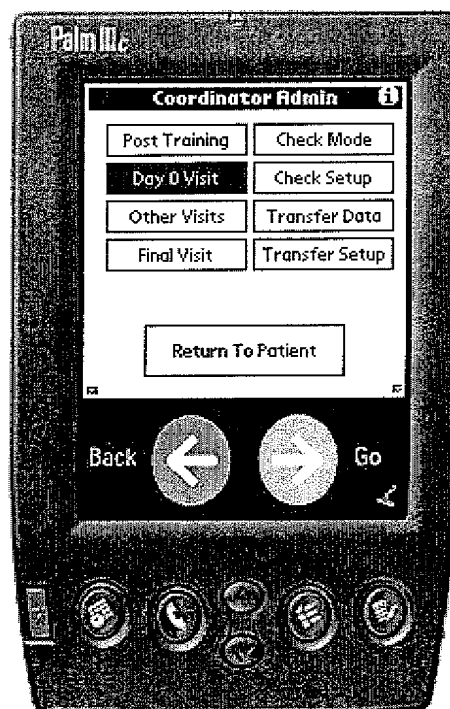
This visit is conducted 2 weeks after training to determine if the patient is eligible to continue in the study. It will also set the timing for the on and off monitoring periods for the remainder of the study.

1. Enter the 2-3-3-4-2 Coordinator Access Code.

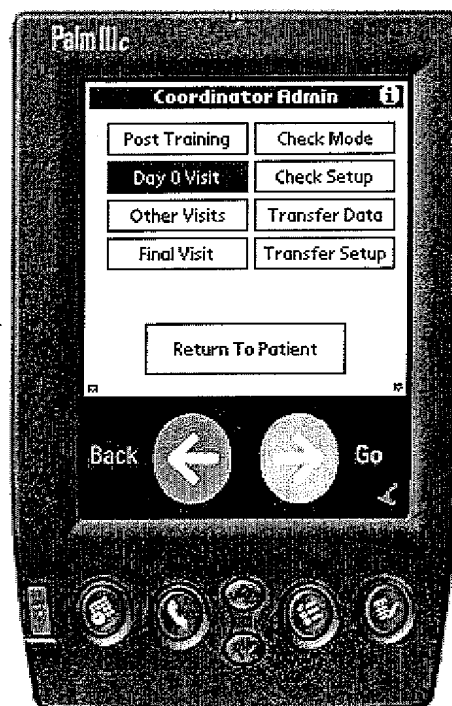


RETIRED

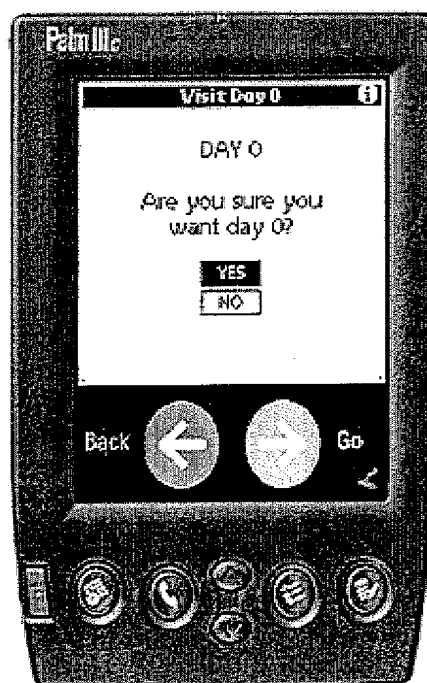
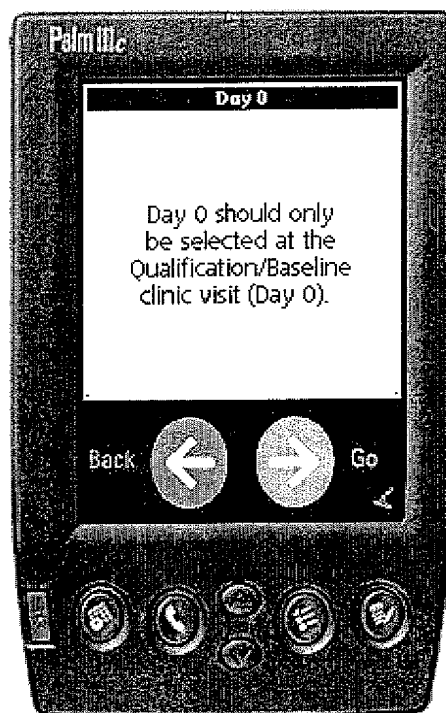
2. After entering the 2-3-3-4-2 sequence, the following screen appears.



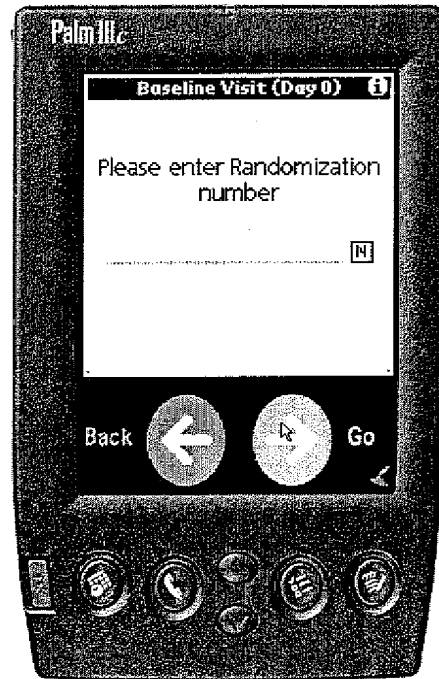
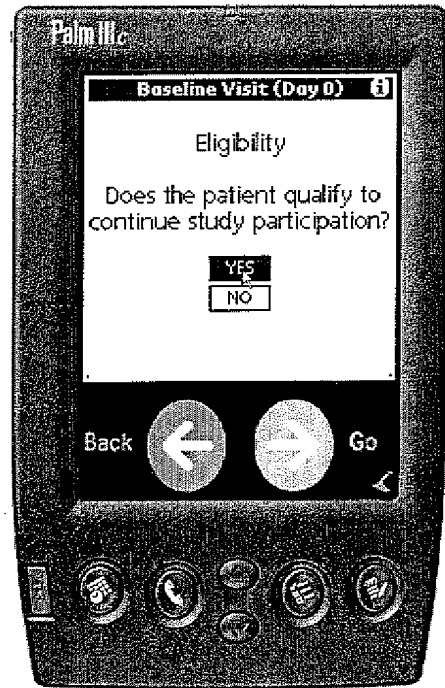
3. Select the Day 0 Visit Button; it is used to help determine if the patient eligible for the study, and record randomization details.



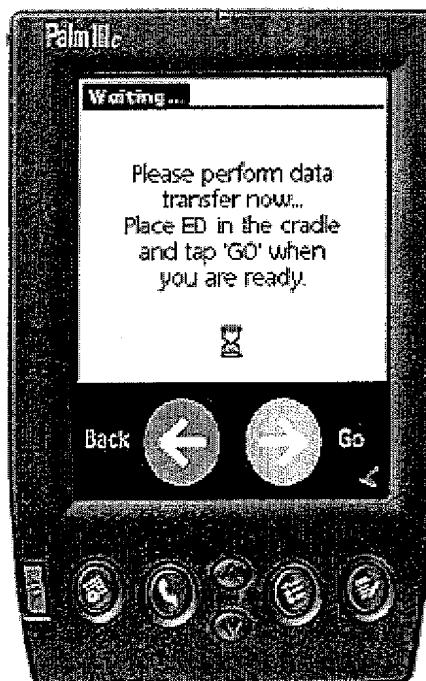
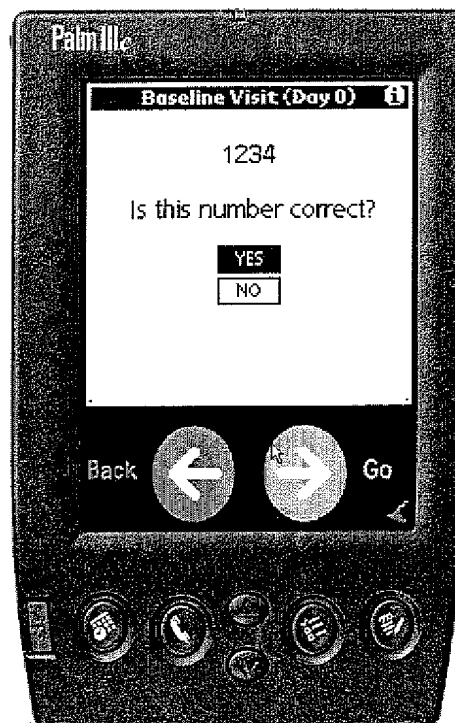
RETIRED



RETIRED



RETIRED

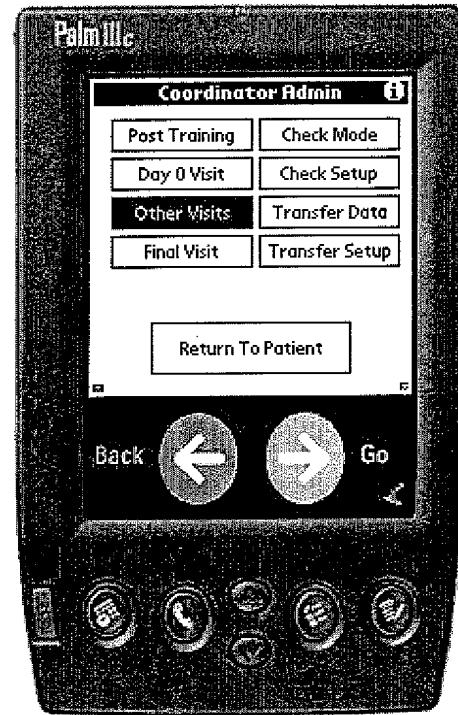


RETIRED

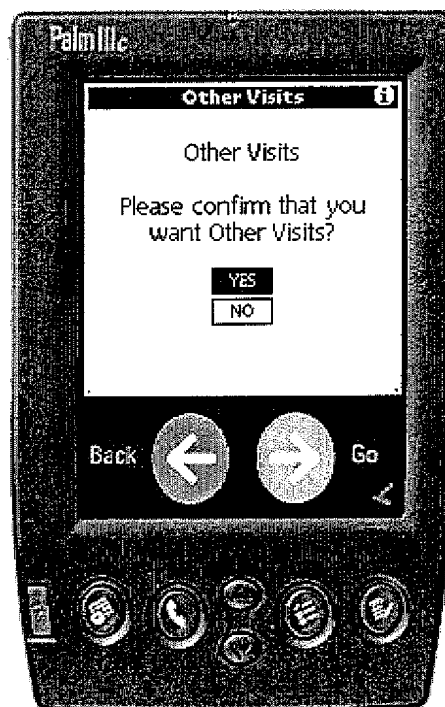
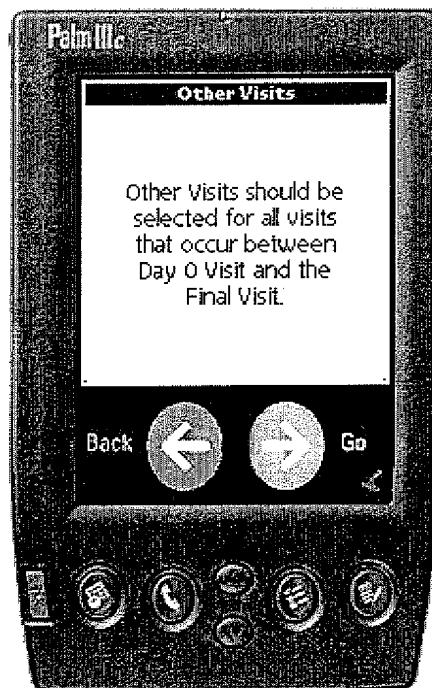
Weeks One, Four, Eight and Twelve Visits

At each of these visits, the patient must bring ED to the clinic. You will need to turn ED on, confirm that you are doing an off-monitoring visit then enter coordinator administration. You will follow the same routine for each visit:

1. You will be asked a series of questions and then you will perform a data transfer, as shown in the following pictorial steps:



RETIRED



RETIRED

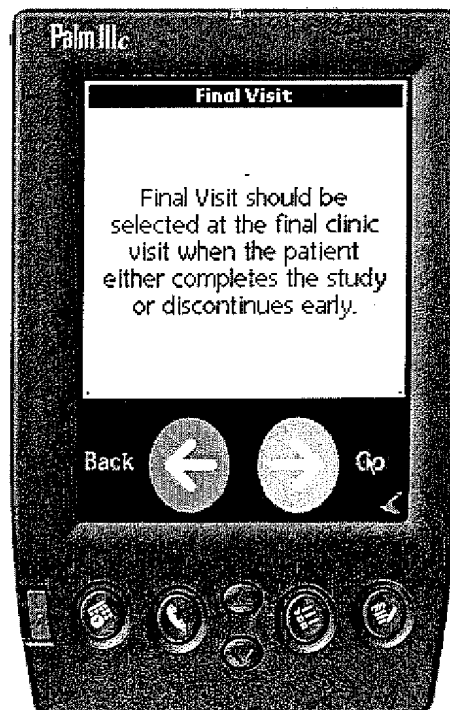
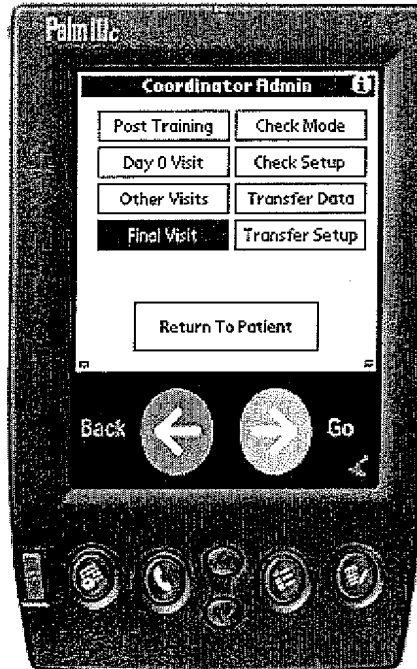


RETIRED

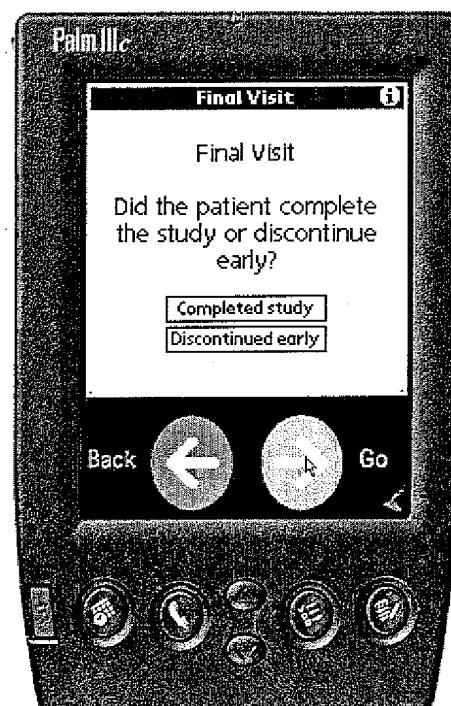
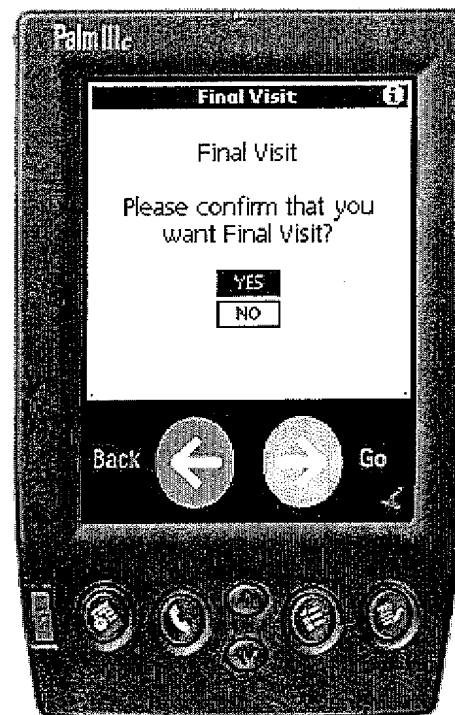
Final Visit (Week 16 or early discontinuation)

Select the Final Visit Button at the last patient visit.

1. You will be asked a series of questions and then you will perform a data transfer, as shown in the following figures.



RETIRED



RETIRED

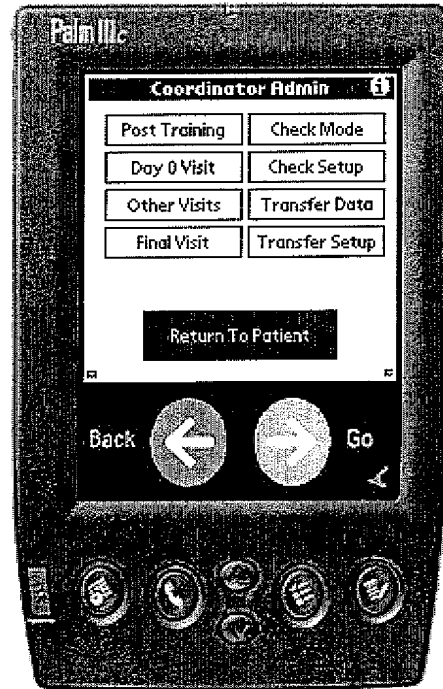


RETIRED

Return to Patient Button

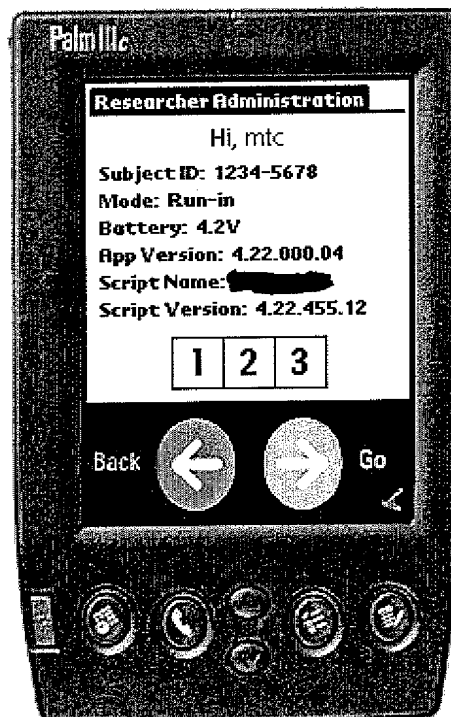
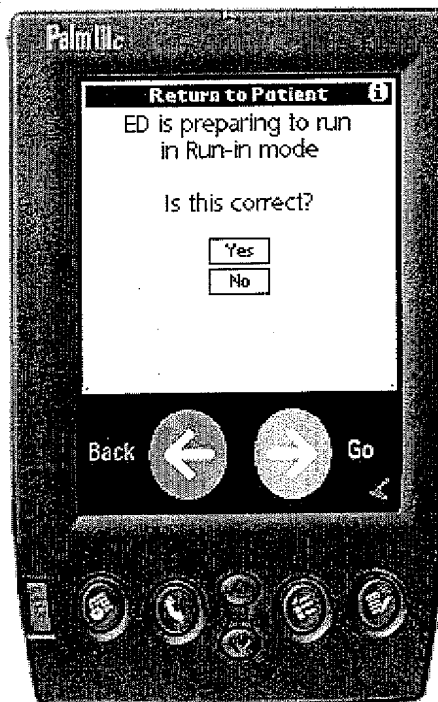
Select this button to return to the 1-2-3 screen. Then, touch the 1-2-1-2-3 sequence to return to the patient's main menu.

1. The following figures show you the series of screens that return you to the patient's main menu.



RETIRED

At this screen, you will confirm that you running in the correct mode. Select 'yes' and tap GO.



RETIRED

Patient Management and Feedback

The invivosystem® uses patient data to help you make real-time decisions and interventions related to patient compliance.

Patient Management and Feedback is broken into four parts:

1. Patient Tracking
2. Protocol Compliance
3. Problem/Issue Identification
4. Protocol Decisions

This section of the manual describes how to log on to and use the invivosystem.com Website to carry out the components of patient management and feedback.

Logging On to invivosystem.com

To carry out these procedures, you will need a Windows based PC with Internet Access and Internet Explorer 5.5.

You will be required to review patient's data on a daily basis, close PPF and DCF for all visits, telephone and clinic and review any associated reports.

Note!

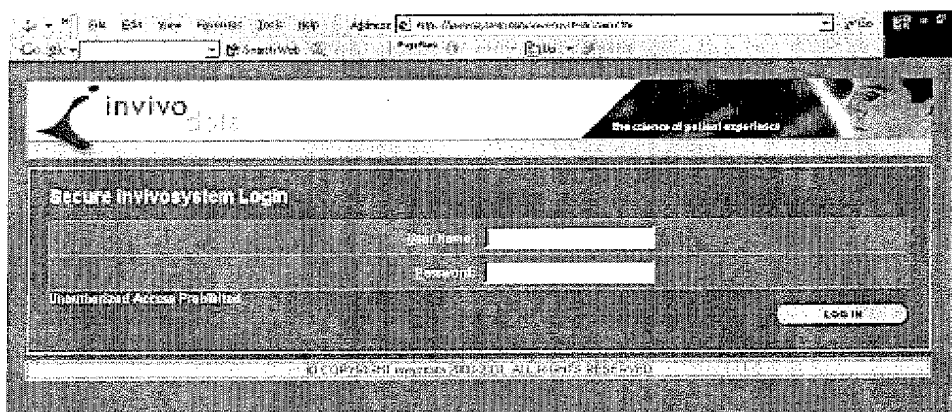
Your user name and password are contained on the Electronic Signature Certificate.

Sample Login Screen

This is the screen you will see when you type in the invivosystem® Website address of www.invivosystem.com.

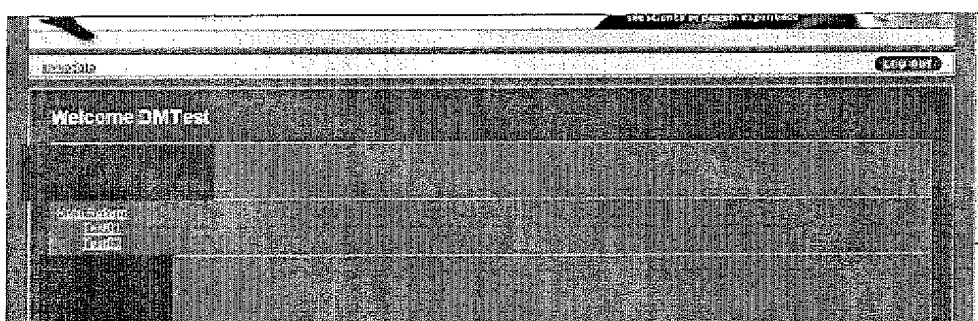
Enter your Username and Password from your Electronic Signature Certificate and click login.

RETIRED



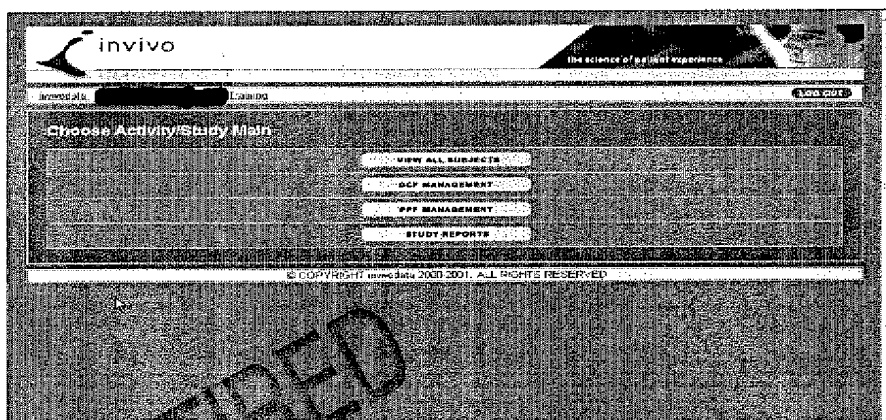
Sample Welcome Screen

This is the screen that you will see after you log in. You will only have access to your site. Click on your site number and you will come to the Choose Activity/Study Main screen.



Sample Choose Activity/Study... Main Screen

Clicking your site's number opens the Choose Activity/Study Main Screen. We will now discuss the parts of the website that will help you track your patients' compliance.



RETIRED

Clicking View All Subjects opens the Subject Summary screen, which allows you to participate in all the data activities that track your patients' compliance.

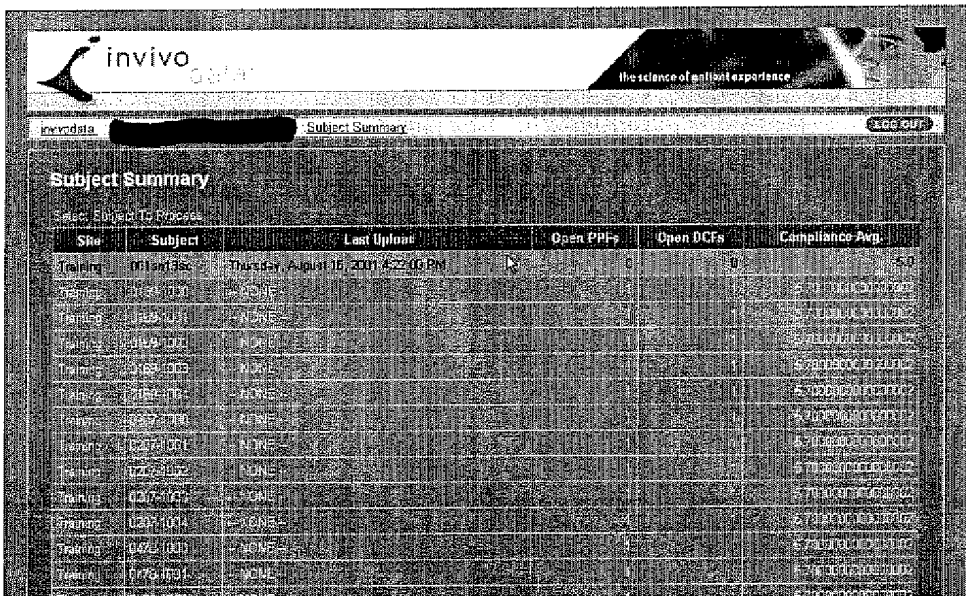
RETIRED

Tracking Patients' Data Transfer

Tracking patients in this study will begin with making sure that data transfers occur every night during On Monitoring.

Sample Subject Summary Screen

To check the date of your patient's last data transfer, double-click on the specific patient whose last transfer date you wish to review.



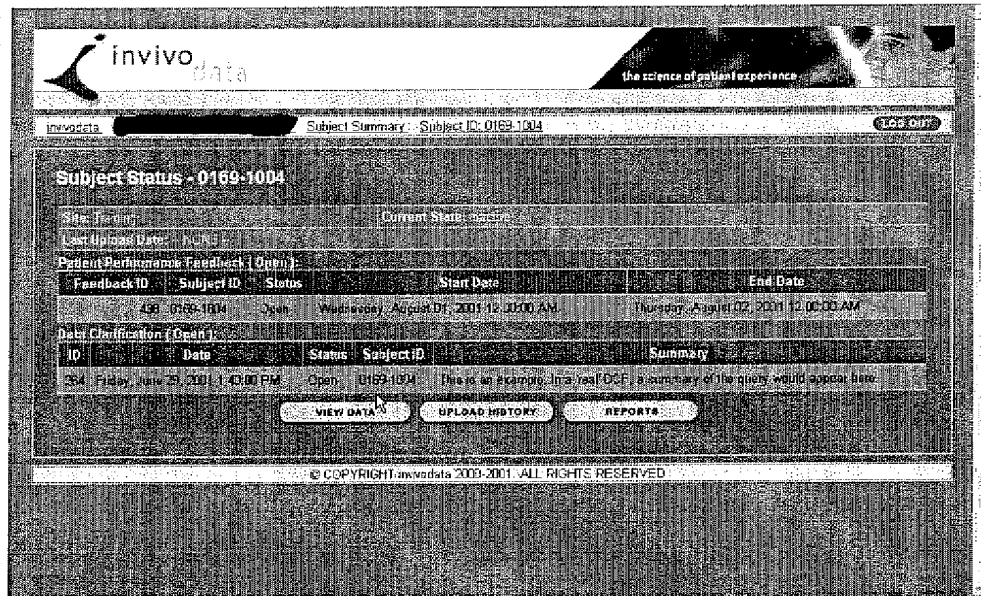
Site	Subject	Last Update	Open PPGs	Open DCGs	Compliance Avg.
Training	00100135	Thursday, August 16, 2001 4:22:00 PM	0	0	50
Training	00100136	NONE	0	0	50
Training	00100137	NONE	0	0	50
Training	00100138	NONE	0	0	50
Training	00100139	NONE	0	0	50
Training	00100140	NONE	0	0	50
Training	00100141	NONE	0	0	50
Training	00100142	NONE	0	0	50
Training	00100143	NONE	0	0	50
Training	00100144	NONE	0	0	50
Training	00100145	NONE	0	0	50
Training	00100146	NONE	0	0	50
Training	00100147	NONE	0	0	50
Training	00100148	NONE	0	0	50
Training	00100149	NONE	0	0	50
Training	00100150	NONE	0	0	50

The Subject Status Screen appears.

Sample Subject Status Screen

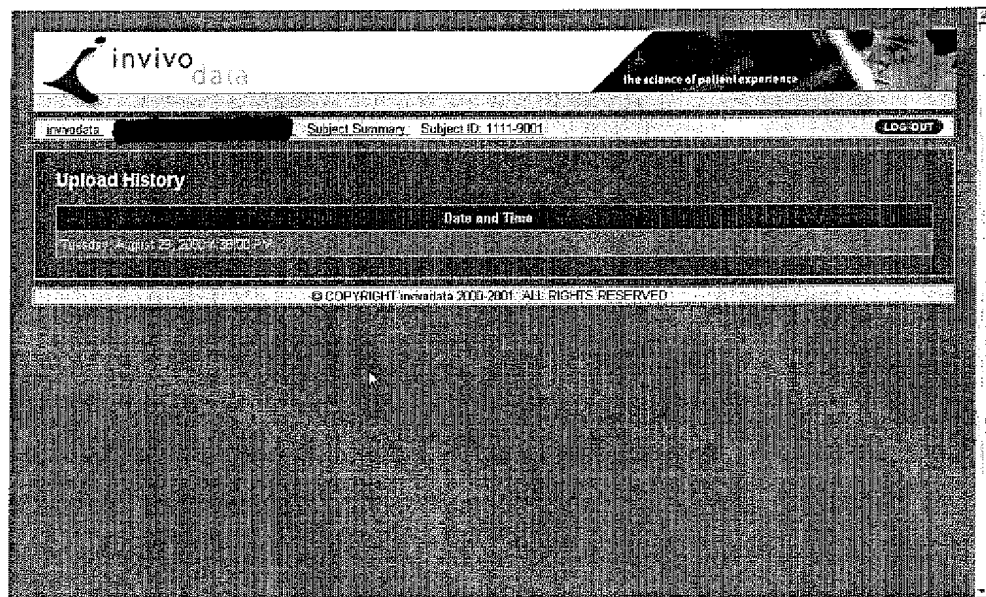
The Subject Status Screen displays summary information about the selected patient. On the Subject Status Screen, click the Upload History button.

RETIRED



Sample Upload History Screen

The Upload History screen displays a chronological history of each of this patient's data transfers.



RETIRED

Protocol Compliance

After you ensure that the patient has been uploading data on a nightly basis, you will then check the reports for protocol compliance.

The steps for checking protocol compliance are:

1. Review the Patient Performance Feedback Form (PPF)
2. Review any associated reports for the PPF or the visit.
3. Review any open Data Clarification Form (DCF)
4. Meet with the patient and review compliance.

Reviewing the Compliance Average

The Compliance Average tells you how well the patient is doing with the protocol on average. The table below gives you an idea what you should be looking for.

Note!

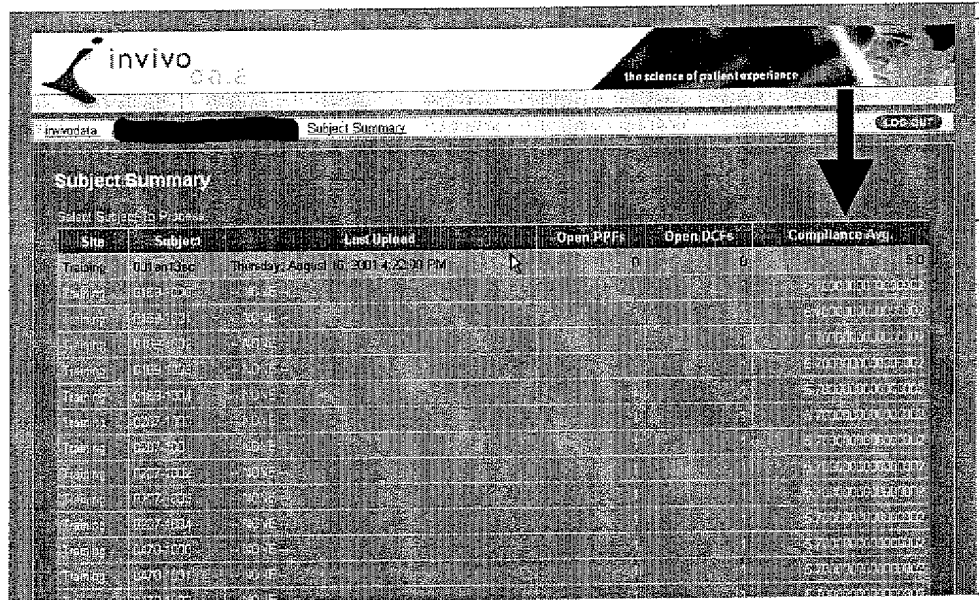
In this study the compliance average is generated from the PPF.

The compliance averages are described below.

1 – 3	Very serious compliance problems. The patient is not complying with most procedures. If protocol allows, discontinuation should be considered.
4 – 6	Serious compliance problems. The patient is not complying with one or more critical procedures. Corrective feedback with patient is essential.
7 – 9	Minor compliance problems. The patient is not complying with minor procedures. Gentle corrective feedback is suggested.
10	No compliance problems. The patient is complying with all study procedures. Reinforce patient for outstanding performance.

To review the Compliance Average, navigate to the Subject Summary Screen. The column to the far right will contain the compliance average.

RETIRED



Site	Subject	Last Update	Open PPFs	Open DCFs	Compliance Avg.
Training	001en000	Thursday, August 10, 2006 4:22:01 PM	0	0	50
001en001	001en001				
001en002	001en002				
001en003	001en003				
001en004	001en004				
001en005	001en005				
001en006	001en006				
001en007	001en007				
001en008	001en008				
001en009	001en009				
001en010	001en010				
001en011	001en011				
001en012	001en012				
001en013	001en013				
001en014	001en014				
001en015	001en015				
001en016	001en016				
001en017	001en017				
001en018	001en018				
001en019	001en019				
001en020	001en020				

Reviewing the Patient Performance Feedback Form

After reviewing the Compliance Average, you will need to review the Patient Performance Feedback Form.

Note!

In this study the PPF will be posted 3 days after the training visit and one and three days after the start of each On Monitoring period.

From the Subject Status screen, double click on the Patient Performance Feedback line and the PPF form will open for you.

RETIRED

invivo data the science of patient experience

invodata [redacted] Subject Summary: Subject ID: 0169-1004 [LOG OUT]

Subject Status - 0169-1004

Site Trainers: [redacted] Patient Status: [redacted]

Last Upload Date: [redacted]

Patient Performance Feedback (Open):

Feedback ID	Subject ID	Status	Start Date	End Date
451	0169-1004	Open	Wednesday, August 01, 2001 12:00:00 AM	Thursday, August 02, 2001 12:00:00 AM

Data Certification (Open):

ID	Date	Status	Subject ID	Summary
54	Friday, June 29, 2001 10:30 PM	Open	0169-1004	This is an example. In a real DCF, a summary of the query would appear here.

[VIEW DATA] [UPLOAD HISTORY] [REPORTS]

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Sample Patient Performance Feedback Form (PPF)

invivo data the science of patient experience

invodata [redacted] Subject Summary: Subject ID: 0169-1004 [LOG OUT]

Patient Performance Feedback

Subject ID: 0169-1004 Site ID: Training Feedback ID: 451

Status: Open Wednesday, August 01, 2001 12:00:00 AM Rating: 5.00

Date Range: Wednesday, August 01, 2001 12:00:00 AM to Thursday, August 02, 2001 12:00:00 AM

Compliance Criterion	Feedback Text
Patient CR	The patient is not taking the medication as directed. The patient is not taking the medication as directed. The patient is not taking the medication as directed.
Medication	The patient is not taking the medication as directed. The patient is not taking the medication as directed. The patient is not taking the medication as directed.
Compliance	The patient is not taking the medication as directed. The patient is not taking the medication as directed. The patient is not taking the medication as directed.
Comments:	This is a sample PPF form. It is intended to be used for the purpose of the exercise. It is not a real PPF form.
Analyst Notes:	Wednesday, August 01, 2001 10:30 PM [redacted]

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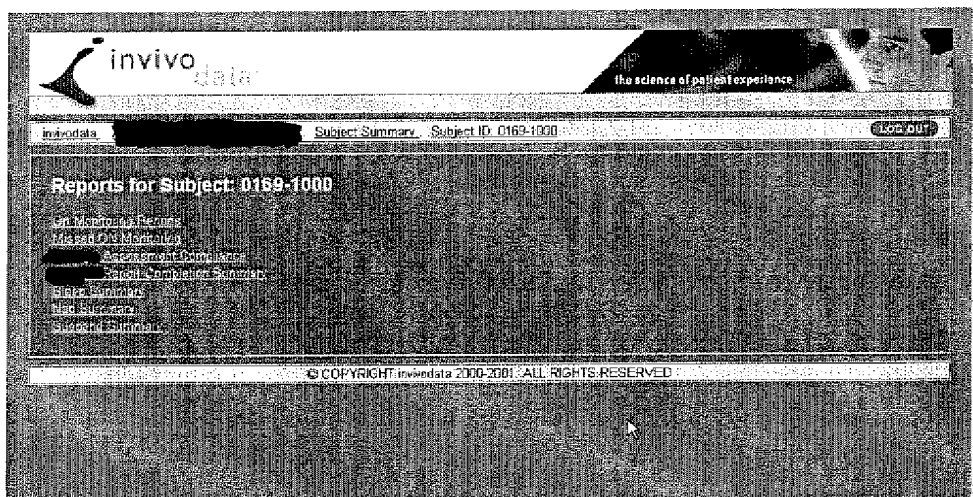
Remember to click on the Feedback Given button every time you review the PPF and review it with the patient.

Patient Reports

The next level of compliance is the Patient Reports. If you see something on the PPF that you would like to investigate further, you can open the related report and view the data.

RETIRED

Navigate to the Subject Status screen and click on the Reports button. You will come to this screen. You can then choose the report or reports you wish to review.



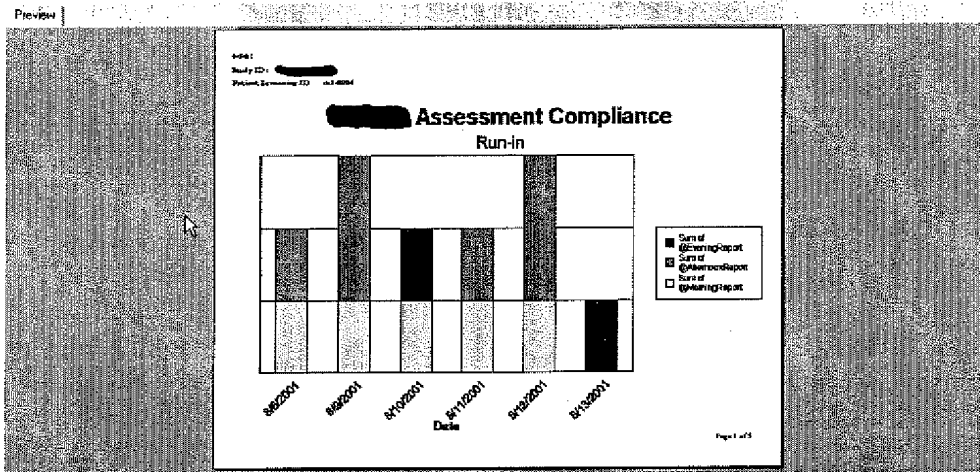
The following is a list of the reports, what the purpose of the report is and when you might need to use the report.

Report Description	Report Purpose	Visit	Implications
On Monitoring Periods	Displays patient's On Monitoring Periods schedule	All	Patient Tracking
Missed 'On Monitoring' Report	Used to track patient compliance with responding to On Monitoring schedule	All	Is patient keeping ED in the cradle during off monitoring periods as instructed?
Assessment Compliance	Used to track patient compliance with completion of daily dry eye reports	All	Is the patient carrying ED with him/her?
Report Completion Summary	Identifies the times and reasons (in red) for missed dry eye reports	All	Is the patient completing
Sleep Summary	Is the patient putting ED to bed every night in the On Monitoring period?	All	Is the patient being compliant with ED during the On Monitoring period?
Nap Summary	Used to track the number of times per day a patient is using Nap	All	Is the patient using Nap for daytime sleeping only?
Suspend Summary	Used to track number of times per day a patient is using Suspend	All	Is the patient using Suspend appropriately?

RETIRED

Examples of each report are shown below:

Assessment Compliance



Report Completion Summary

Preview

9/5/01
Study ID: [REDACTED]
Patient Screening ID: tst2-0004

Report Completion Summary

Date and Time	Monitoring Period	Alarm	Status
8/8/01 12:52 pm	Run-in	Morning	Completed
8/8/01 6:05 pm	Run-in	Afternoon	User Delay
8/8/01 6:20 pm	Run-in	Afternoon	Completed
8/9/01 12:25 am	Run-in	Evening	Completed
8/9/01 1:05 am	Run-in	Morning	Completed
8/9/01 12:33 am	Run-in	Evening	Completed

RETIRED

Missed On Monitoring Report

Preview

9/5/01
Study ID :
Patient Screening ID: tst2-0052

Missed ED On Monitoring

Date	On Monitoring Notification
8/29/01	Completed
9/26/01	Completed
10/24/01	Completed
11/21/01	Missed

Sleep Summary Report

Preview

9/5/01
Study ID :
Patient Screening ID: TST2-0004

Sleep Table

Date and Time Patient put ED to Sleep	Time Patient put ED to Wake	Actual Time of Wake	Duration of Sleep
8/8/2001 12:11:00PM	12:09 AM	8/8/2001 12:11:00PM	0 hr. 0 min.
8/9/2001 12:25:00AM	12:30 AM	8/9/2001 12:27:00AM	0 hr. 2 min.
8/9/2001 12:33:00PM	12:39 PM	8/9/2001 12:39:00PM	0 hr. 6 min.
8/10/2001 1:23:00AM	01:28 AM	8/10/2001 1:28:00AM	0 hr. 5 min.
8/10/2001 7:27:01AM	3:30 PM	8/10/2001 3:34:00PM	8 hr. 7 min.
8/12/2001 4:00:00AM	04:05 AM	8/12/2001 4:01:00AM	0 hr. 1 min.
8/12/2001 4:53:00PM	5:08 PM	8/12/2001 5:08:00PM	0 hr. 15 min.
8/13/2001 4:57:00AM	05:02 AM	8/13/2001 5:02:00AM	0 hr. 5 min.
8/13/2001 5:02:00AM	06:00 AM	8/13/2001 5:02:00AM	0 hr. 7 min.

RETIRED

Nap Report

Preview

9/6/01
Study ID: [REDACTED]
Patient Screening ID: TST2-0016

Subreport:Report-Header.rpt

Nap Table

<u>Date and Time Patient set ED to Nap</u>	<u>Time Patient set ED to Wake</u>	<u>Actual Date and Time of Wake</u>	<u>Duration of Nap</u>
8/10/2001 3:45:00PM	4:00 PM	8/10/2001 4:01:00PM	0 hr. 16 min.
8/11/2001 8:01:00AM	08:11 AM	8/11/2001 8:12:00AM	0 hr. 11 min.
8/11/2001 8:13:00AM	08:27 AM	8/11/2001 8:57:00AM	0 hr. 44 min.
8/11/2001 9:01:00AM	09:16 AM	8/11/2001 9:11:00AM	0 hr. 10 min.
8/11/2001 9:18:00AM	11:17 AM	8/11/2001 9:19:00AM	0 hr. 1 min.
8/12/2001 10:01:00AM	12:00 PM	8/12/2001 1:14:00PM	3 hr. 13 min.
8/13/2001 10:12:01AM	12:15 PM	8/13/2001 12:18:00PM	2 hr. 6 min.

Suspend Report

Preview

9/5/01
Study ID: [REDACTED]
Patient Screening ID: K12-0006

Suspend Table

<u>Date and Time Patient set ED to Suspend</u>	<u>Date and Time Suspend Ended</u>	<u>Duration of Suspend</u>	<u>Suspend Ended by ED or Patient</u>	<u>Reason for Suspend</u>
8/10/01 1:09 pm	8/10/01 1:10 pm	1 min.	Break Suspend Patient	Driving
8/10/01 1:12 pm	8/10/01 1:14 pm	2 min.	Break Suspend Patient	Other
8/10/01 1:17 pm	8/10/01 1:19 pm	2 min.	Break Suspend Patient	Quiet Place
8/10/01 1:52 pm	8/10/01 2:23 pm	31 min.	End Suspend (Timeout)	Meeting/Job
8/10/01 2:32 pm	8/10/01 3:06 pm	34 min.	End Suspend (Timeout)	Driving

Giving Patient's Feedback

After you review the Patient Performance Feedback form with the patient, you will click on the Feedback Given button. You will then get a confirmation screen asking you to enter your four-digit password from your Electronic Signature Certificate. This is your signature indicating that you have given this feedback to the patient, and the patient understands.

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Identifying and Resolving Issues

After reviewing compliance, you will need to check for any data queries by reviewing the Data Clarification Form (DCF).

Reviewing any DCFs will be the third component of the patient management cycle.

To check on DCFs go to the Subject Status screen and click in the Data Clarification area and you will open the Data Clarification Form.

invivo data
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invivodata Subject Summary Subject ID: 0189-1004

Subject Status - 0189-1004

Site: Tr 003 Current Status: Active

Last Upload Date: 10/25/08

Patient Performance Feedback (Open):

Feedback ID	Subject ID	Status	Start Date	End Date
15	0189-1004	Open	Wednesday, August 06, 2008 12:00:00 AM	Thursday, August 02, 2009 12:00:00 AM

Data Clarification (Open):

ID	Date	Status	Subject ID	Summary
254	Friday, June 29, 2007 1:40:00 PM	Open	0189-1004	This is an example for a test DCF. A summary of the query would appear here.

VIEW DATA UPLOAD HISTORY REPORTS

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Sample Data Clarification Form (DCF)

The screenshot shows a web-based form titled "Data Clarification Form". At the top, there are tabs for "invivosys", "Subject Summary", and "Subject ID: 0169-100". The form fields include:

- Subject ID: 0169-100
- Date: 11/11/2011
- Time: 11:11 AM
- Query: [Empty text area]
- Resolution: [Large text area for response]

A "SUBMIT" button is located at the bottom right of the form. The footer of the page reads "© COPYRIGHT invivosys 2003-2011. ALL RIGHTS RESERVED".

Type your response in the query resolution space and click submit.. You will then be asked to confirm your submission with your 4-digit password from your Electronic Signature Certificate.

Protocol Decisions

In this study, protocol decisions will not be based on any of these reports. They are here to help you maintain good patient compliance with study protocol and insure strong primary efficacy data.

Patient Feedback Session

Reviewing progress with your patient is an essential step in the process

The recommended process is for you to review the PPF, review any related reports, and review any DCF that have been posted.

Patient Progress should then be discussed with the patient, starting with the positive, following with any corrective feedback that needs to be shared, and ending with any issues raised in DCF format.

Issue Resolution should be the last thing discussed with the patient as stated above. Once you have obtained the resolution to issues, make sure you respond to the DCF as discussed above.

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Patient Completion/Termination

At the final study visit you will select the Final Visit button and follow the instructions discussed on page 47. Remember: when you've done the final data transfer, retain ED and the Data Transfer Kit. Return ED and the Data Transfer Kit using the airbills that are provided. Check the User's Guide for specific instructions.

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Homework for You

Objective: To help you put everything you've learned together about how to use the invivosystem.

You complete the homework in your own clinic environment with a partner to demonstrate that you understand how to train patients on ED and use the invivosystem to manage your patients' compliance.

Homework Materials

1. A prepared ED
2. ED's Data Transfer Kit
3. Patient Training Flip Book
4. The User's Guide
5. Homework Completion Instructions

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Overview of the Training Process

Set up ED	Use ED	Review Web site	Subject Visit
Steps Follow instructions in User's Guide	Steps Train your partner as you would a real patient <i>Use the flipbook</i>	Steps Partner performs interviews and one data transfer using ED's Data Transfer Kit.	Steps Review PPF, DCF and reports prior to partner's 'visit'.
			Steps Share feedback and resolve DCFs with Partner as you would a patient.

When setting up ED for your partner, use the subject ID that has been assigned to you in the Homework Completion Instructions.

Train a partner as you would a patient; using the Patient Training Flipbook. Have your partner carry ED the same as a patient would; including putting ED to bed and transferring data.

Note!

Remember to put ED into Run- In mode by doing the V1-Post Training Data Transfer when you've completed the training of your partner.

Have your partner return the next day. Review your partner's data prior to the visit as you would a real patient. Review PPF, DCF and any necessary reports. During the visit follow the Day 0 Visit routine, provide feedback and close the PPF, review and close the DCF then send your partner home. Remember to keep ED and the Data Transfer Kit.

When these tasks are completed, invivodata will notify you that your website username and password are now active for the study website.

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FAQs

Objective: To help you answer patients' and coordinators' frequently asked questions about using ED.

Patient Q&A

1. **Do I have to put ED to sleep and set the alarm every night?**
Yes. ED does not remember your wake up time from one day to the next
2. **If I don't do something can I go back later?**
Within each interview, you may go back as needed to change a response. However, once you've entered your password, you can no longer change that assessment
3. **Can I accidentally destroy the information I am sharing with ED?**
No, if you get stuck just keep trying. Remember the key instructions – tap the ON key to turn ED on, read the screen, make a choice, then tap GO.
4. **What happens if I need to travel?**
Let your study coordinator know if you will be traveling. You will receive data transfer failure notices in the morning without your data transfer kit, so your study coordinator needs to know when you are away. Be sure that you have been letting ED fully charge on his cradle each night before leaving.
5. **What if I lose ED?**
You will need to contact your site immediately.
6. **Is it really necessary to take ED with me when I leave the house?**
Yes. You must keep ED with you at all times during the 'On Monitoring' periods of the study. It is very important for you to not miss any 'beeps'. If ED is not with you, you won't be able to do that. During off monitoring periods, leave ED charging on the cradle.

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7. **Can I take ED out of the case and carry it in my pocket?**

No. It's very important that you carry ED in the case to protect him.

8. **Can I carry ED in my pocketbook?**

No. It's important that you don't carry ED concealed in another bag or garment. Doing so will muffle ED's beeps and make it very difficult to hear.

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Coordinator Q&A

1. **What is the invivodata Website address?**
 - a. www.invivosystem.com
2. **What happens if the data fails to transfer?**
 - a. Is the correct patient ID displayed?
 - b. Is the modem plugged in and turned on?
 - c. Is the cradle connected to the modem?
 - d. Is the plug plugged tight into the modem?
3. **What should I do if ED won't take my initials and password?**
 - a. Did you enter what was assigned on the Electronic Signature Certificate?
 - b. Is the ED username being used, not the website?
 - c. Is ED displaying the Study Coordinator Initials and Password screen?
4. **What should I do if I can't get into Coordinator Administration?**
 - a. Clarify your understanding of the buttons at the bottom of ED, e.g., go from left to right, 1,2,3,4 by re-reading "Error! Reference source not found.", on page Error! Bookmark not defined. of this book.
5. **What should I do if I can't log in?**
 - a. Have you signed and returned your Electronic Signature Certificate?
 - b. Are you using the Website username and password assigned on the Electronic Signature Certificate?
 - c. If you are a new coordinator, have you contacted your CRA and invivodata to obtain a Website username and password?
6. **Do I need to put ED in Run-In after I train the patient?**

No. When you do a data transfer after training, the software will automatically do the switch for you.

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